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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,542	12/27/2001	Kyung-Ja Han	2669-0117P	9476
2292	7590	12/03/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			ZEMAN, ROBERT A	
		ART UNIT	PAPER NUMBER	
		1645		
DATE MAILED: 12/03/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/026,542	HAN, KYUNG-JA
	Examiner	Art Unit
	Robert A. Zeman	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 14 September 2004.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-7 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## DETAILED ACTION

The amendment and response filed on 9-14-2004 are acknowledged. Claims 1 and 2 have been amended. Claims 3-7 have been added. Claims 1-7 are pending and currently under examination.

### *Claim Rejections Withdrawn*

The new matter rejection of claims 1-2 under 35 U.S.C. 112, first paragraph, based on the recitation of the phrase “peripheral blood sample in **hypotonic solution** with PE conjugated anti-hemoglobin (anti-Hb) antibody” is withdrawn in light of the amendment thereto.

The new matter rejection of claims 1-2 under 35 U.S.C. 112, first paragraph, based on the recitation of the phrase “2ml” is withdrawn in light of the amendment thereto.

The new matter rejection of claims 1-2 under 35 U.S.C. 112, first paragraph, based on the recitation of the phrase “wherein said diagnostic method of **hemolytic anemia** shows stained red blood cells of more than 1%”. is withdrawn in light of the amendment thereto.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is withdrawn in light of the amendment thereto.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as rendered vague and indefinite by the use of the phrase “wherein said diagnostic method of

hemolytic anemia shows stained red blood cells of more than 1%” is withdrawn in light of the amendment thereto.

***Claim Rejections Maintained and New Grounds of Rejection***

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons set forth in the previous Office action in the rejection of claims 1-2. The claim(s) still contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

**Applicant argues:**

1. The proportion of stained RBCs from MAHA patients is statistically higher than those from normal patients.
2. The reference range is set at  $\pm 2$  standard deviations (SD) hence the cutoff value of the normal control is 1.01% and therefore one of skill in the art is fully able to distinguish normal patients from patients with hemolytic anemia.
3. The results in patients with malaria and spherocytosis are also statistically significant.
4. Data from postsplenectomy patients were not different from normal patients indicating the ability of the instant method to discern between “old” and “active” hemolysis.

Applicant’s arguments have been fully considered and deemed non-persuasive.

The instant invention is drawn to methods of diagnosis hemolytic anemia (generally) and MAHA (specifically), which comprise detecting the number of damaged red blood cells by treating a peripheral blood sample with a PE conjugated anti-hemoglobin antibody; diluting said sample in saline and analyzing said sample by flow

cytometry. Patients can either be malarial patients, spherocytosis patients or postsplenectomy patients. The diagnosis of hemolytic anemia is made when more than 1% of the red blood cells in the sample are stained. Based on the instant disclosure the claimed method would not allow one of skill in the art to determine if a given patient suffers from hemolytic anemia. The specification discloses that the use of the claimed method resulted in the staining of  $2.95\% \pm$  a standard deviation of 2.95 of the red blood cells from samples obtained from patients with microangiopathic hemolytic anemia (MAHA) compared to  $0.55 \pm 0.23\%$  in samples from normal patients (control). There is no statistical difference between the results obtained from the MAHA samples and the normal samples. Moreover, there is no statistical significance between the results obtained from the MAHA samples and samples from malaria patients, postsplenectomy patients and patients suffering from spherocytosis. As disclosed by the specification the p values for the MAHA, malarial and spherocytotic samples were  $P=0.000$ ,  $P=0.001$  and  $P=0.000$ , respectively (see pages 5 and 6 of specification). These values indicate that the associated data sets have no statistical significance. Consequently, based on the specification one would not be able to determine whether a given patient was suffering from hemolytic anemia by using the claimed method. Therefore, the instant invention is not enabled.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*L. R. F. Smith*  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Robert A. Zeman  
November 30, 2004